

REMARKS BY  
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TO THE ANNUAL MEETING OF  
PMA'S LAW SECTION  
MARCH 16, 1987

"The Outlook in the 100th Congress for  
Legislation Affecting the Pharmaceutical Industry"

Much will be written about the Congress that convened in January.  
It is the historic 100th Congress of the United States.

I sense a renewed vigor and determination in this Congress to  
address the hard domestic and international issues that confront our  
country. Those of us who care about public health and health policy  
view the 100th Congress as an opportunity to renew our commitment to  
solving our most pressing health problems.

A salient characteristic of the American psyche is that we prefer  
to talk about the next problem, rather than rest on our laurels. But,  
we have much to be proud of. Let's talk about our successes:

- o We have a larger number of highly trained physicians than ever  
before.
- o We have the world's best medical technology and finest  
pharmaceuticals for diagnosing and treating disease.
- o We have dramatic breakthroughs in biomedical research on what  
seems like a weekly basis.

- o The public's ever-increasing understanding of diet and exercise is raising our level of fitness and well-being.

But it is also good not to be too complacent about our successes. We cannot afford to be. Let me give you four reasons why.

- o There are 37 million Americans with no form of health insurance. Even though many are poor, they do not get even the meager benefits of Medicaid. Surprisingly, many of the uninsured work in low-paying part- or full-time jobs.
- o The AIDS epidemic races ahead jeopardizing the lives of millions in this country and abroad. While the death toll mounts, we at least are beginning to see some signs of progress in drug therapy and our understanding of the disease itself. We are not even remotely prepared, though, for the huge costs of treating the thousands of new patients who will become hospitalized.
- o Health care costs for all of us continue <sup>their rapid rise</sup> ~~to race ahead~~ despite record low inflation. And to make matters worse, our efforts to hold down hospital and doctor costs have increased the use of other services, like nursing homes and home health care, that are not covered by insurance. And as prescription drug therapies <sup>gain</sup> ~~continue to increase~~ in importance in treating illnesses - and the prices of those drugs continue to increase

- out-of-pocket health care costs ~~continue~~ to rise dramatically.

- o Our rapidly aging population will present the health care system of the 21st Century with overwhelming new demands that we are not prepared to meet. We talk of "catastrophic" health insurance for the aged, yet we leave out coverage for nursing home care and drugs. Several years in a nursing home or a decade of \$200 a month drug costs are no less a medical and financial catastrophe than a prolonged hospital stay.

This short list constitutes some of the most difficult of the matters before the 100th Congress. There are many more of great importance.

#### Pharmaceuticals and Health Care

The 100th Congress will be a busy time for those of us interested in pharmaceuticals and health care. Just as in the last two Congresses, where we worked together on a number of legislative initiatives, you will again be the focus of Congressional attention.

I am pleased that I have been able to work with the PMA and your companies on a number of very important bills.

#### Areas of Agreement

In 1983, after working through a number of different approaches to promoting the development of orphan drugs, we joined forces to pass the Orphan Drug Act. Immeasurable good has come from the law.

Over 120 drugs for rare diseases are now designated and either approved or under development. Your industry and the PMA have made a significant contribution to the hopes and lives of the millions of Americans who suffer from rare diseases. Now that we have a mechanism for focusing the necessary resources on orphan drugs, I am confident we will continue our successes for years to come.

In 1984, the PMA and most of its members joined a virtually unanimous Congress in passing the generic drug and patent term restoration law. I know that some drug companies believe they lost more than they won. I understand that sentiment. I also believe we all agree that the public deserves price competition when patents have expired.

The law has been a resounding success. The public is benefitting from lower prices for generics of off-patent drugs. Your companies have the substantial incentive of knowing that your reward for good research is five more years of patent life.

In 1985 and 1986, I spent many hours with the representatives of your companies discussing the export of unapproved drugs and vaccine compensation legislation. The result should well serve your industry and the public.

I am satisfied that the drug export bill can protect vulnerable consumers around the world. In addition, your companies have the new, and important, option of building your production plants in the U.S.

The vaccine compensation legislation was long overdue. Vaccines have been public health miracles. In 1952, there were 57,000 cases of paralytic polio; last year there were 4.

We cannot allow the supply of current vaccines to be jeopardized. We cannot tolerate disincentives for aggressive new research to improve them and to make new ones.

The vaccine compensation program protects children who are hurt in the line of public duty. It gives your companies greater certainty about the market place in which you operate. Everyone is better off for its passage.

#### Areas of Disagreement

As is expected, we also have disagreements. Those of you who have visited with me in Washington, or heard me speak, know that I feel strongly about the prices of your products.

#### Prescription Drug Prices

It appears to me that in 1981 your companies embarked on a new

pricing strategy. It is called "whatever the market will bear". Unfortunately, when it comes to essential prescription drugs, your customers have no choice. They will bear whatever you charge.

The elderly use 30 percent of the prescription drugs in the U.S., but Medicare does not pay for drugs. Moreover, nationwide data show that 75 to 80 percent of the drugs in the U.S. are bought without any insurance, leaving consumers with the full burden of increased costs.

And consumer costs have skyrocketed. At my Subcommittee's July 15, 1985 hearing, we documented the unprecedented rise. Between 1981 and June, 1985, the CPI increased 23 percent. During the same time, drug manufacturer wholesale prices rose 56 percent. Many of the top-selling drugs rose even faster.

These enormous increases continued in 1986. Double digit price increases were commonplace. As you probably know, my Subcommittee will be conducting another hearing on prices in late April of this year.

If prices continue to skyrocket, I believe the fundamental balance of our patent system will be distorted. We award monopolies to innovators. But when the innovation is an essential drug, we cannot allow a private enterprise to price sick people out of the market.

In the short run, the public and the health care system are the losers from high prices. In the long run, though, I have no doubt that your companies will suffer.

Your image as caring for the patients treated by your drugs is already tarnished. At some point, the public will turn to government for help.

I am already prepared to begin exploring fair mechanisms for holding prices to reasonable levels. The Canadian compulsory licensing system is one way to insure price competition at an earlier stage. The time has come to evaluate the implications of such a system in the U.S.

### Generic Drugs

Pharmaceutical companies have done more than just raise prices for off-patent drugs in response to new market pressures. Many companies have also engaged in anti-generic activities.

On one hand, many large research-oriented companies are buying generic firms or starting their own generic divisions. On the other, they are engaging in an anti-generic campaign calculated to discourage generic use and boost corporate revenues.

The most recent chapter is the company-funded study of generic prices. Its conclusion, that generics really are not less expensive, is being touted with great fanfare by public relations firms to doctors, the press and the public.

One important fact is omitted. The study was done in 1984, prior

to the expansion of the generic approval system. Since 1984, nine of the top ten selling drugs have gone generic. Numerous generic companies make each of them, so the prices have been driven quite low. I say, be honest with the American people. Repeat the study now with 1986 prices.

An industry that makes generics in private while lambasting them in public will eventually lose credibility and reputation. To think otherwise is cynical and short changes the American people.

#### Agenda for 100th Congress

I said there would be much legislative activity in the 100th Congress that is of interest to the pharmaceutical industry. Let me give you some details.

#### Generic Animal Drugs

In 1986, Congress considered, but failed to pass legislation for generic animal drugs. The bill was modeled after the 1984 law. It would have created a generic approval system for animal drugs and provided patent term restoration for brand name animal drugs. The bill failed in the Senate because several companies insisted on special transition rules to protect drugs already on the market.

Similar legislation will be considered again this year.



### Drug Diversion

Congressman Dingell's drug diversion bill also bogged down last year in an end-of-the-session dispute over free drug samples. As you know, that bill has been reintroduced. I understand an agreement has been reached on sampling. We will be moving the legislation, possibly as early as this week.

### Orphan Drugs

A number of problems with the Orphan Drug Act have been identified and must be addressed. We desperately need additional grant funds for research on drugs that companies will not sponsor.

We also must clarify who has the right to receive the seven years of market exclusivity. Under current law, when two companies simultaneously develop an orphan drug, the first company that is approved gets the right to market the drug and the second gets nothing. We must find a way to reward orphan drug development that does not discourage independent and simultaneous work by other companies.

### Drug Coverage

One of the most important out-patient health benefits that is not covered by Medicare and not usually covered by private insurance is prescription drugs. My immediate concern is for the elderly who are but 11 percent of the population and yet consume 30 percent of the

drugs.

Out-patient drug costs are the second highest out-of-pocket expense for the elderly -- behind nursing home care. For many who receive nothing but Social Security checks, the choice each month is between their medicine and their rent or food. Our sick elderly citizens deserve far more from us.

Medicare coverage for drugs could be quite expensive, especially by the standards of today's budget. But the failure to follow a doctor's prescription is a "medical catastrophe" just as the extended hospital stay that Medicare doesn't cover is a financial catastrophe. In fact, not taking the necessary drugs could produce the very catastrophic illness we all want to protect our seniors against.

The Congress will be considering how to assure our elderly that essential drugs will be available to them.

## AIDS

Without question, the most urgent problem facing the 100th Congress is the AIDS Epidemic.

The Public Health Service estimates that within 5 years we may be paying \$16 billion a year for AIDS medical care alone -- equal to about 25 percent of the entire Medicare budget. The National Academy of Sciences says this is a severe underestimate.

A sizable portion of these costs will be Federal costs, especially as private insurers redline those people who have been exposed.

But as best we can tell, there is no serious planning for how these costs will be borne by the Medicaid and Medicare programs. The Health Care Financing Administration is planning budgets as if the need for health services will be steady, not as if we are about to enter a period of greatly increased need for services.

#### Medicaid Reimbursement for Generics

~~939~~ Many of you are probably familiar with the Medicaid Maximum Allowable Cost (MAC) program that we suspended in 1983. The MAC Program was Medicaid's way to limit reimbursement to pharmacists to the cost of generic drugs, when they were available.

The Department of Health and Human Services cited problems in setting fair reimbursement levels and minimal savings that made the program unimportant. I agreed in 1983, but the 1984 generic drug law changed things.

The Department of Health and Human Services has yet to come forward with a new proposal. An Administration that proposes \$70 billion in Medicare and Medicaid cuts in the next five years certainly should be expeditious in renewing the generic reimbursement program.

If new regulations are not forthcoming, legislation will be.

### Medical Device Regulation

I also intend to push ahead with my bill to reform medical device regulation. Current law demands far more than FDA's meager resources can deliver. It is time to set new priorities. It is time to focus FDA's attention on those matters with the greatest impact on consumer health and safety.

### Closing

That is the list of potential Congressional legislation so far. New issues arise every day. We learned last week that AZT will cost \$7000 - \$10,000 per person per year. Government will have to step in, but the Federal government cannot afford such excessive prices.

We also heard that the Food and Drug Administration is proposing new regulations to allow experimental drugs for life-threatening conditions to be sold to anyone during clinical studies. As I understand the proposal, sale could occur even before there are results from the first human clinical study.

These new developments will require our attention. As you can see, the 100th Congress will be memorable for more than its number. Legislation will be coming fast and furious. For those interested in the health care marketplace it will be a decisive year for policy and

practical economics.

Thank you.